SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6741–6780

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted in whole or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear, in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6741. Ferbetex tablets. (F.D.C. No. 45801. S. No. 32–280 R.)

QUANTITY: 287 50-tablet btls. at Santurce, P.R.

SHIPPED: 2–28–61, from Los Angeles, Calif., by Strand Pharmacal Corp.

LABEL IN PART: "Ferbetex (Improved) Formula Per Tablet * * * Folic Acid 0.4 mg. * * * 50 Tablets Strand Pharmacal Corporation, Los Angeles, California * * * Dosis: 2 Tablets with Meals or as Prescribed."

LIBELED: 5–16–61, Dist. P.R.; amended libel 5–23–61.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof, since the article, under the directions for use, would supply 2.4 milligrams of folic acid daily.

DISPOSITION: 6–22–61. Default—destruction.